

Exhibit 19-1

*State of California ex rel. Ven-A-Care of the Florida Keys, Inc. v.
Abbott Labs, Inc. et al., Civil Action No. 03-11226-PBS*

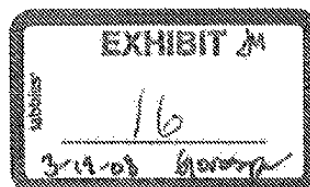
**Exhibit to the November 25, 2009 Declaration of Philip D. Robben
in Support of Defendants' Joint Motion for Partial Summary Judgment**

REPORT BY THE AUDITOR GENERAL OF CALIFORNIA

HOW MEDICAL AND OTHER HEALTH CARE PROVIDERS
MANAGE THEIR PHARMACEUTICAL EXPENDITURES

P-062

AUGUST 1991



CAAG/DHS0071157
CAAG/DHS0071157 [D]



Kurt R. Sjöberg, Auditor General (acting)

State of California
Office of the Auditor General
660 J Street, Suite 300, Sacramento, CA 95814
Telephone: (916) 445-0255

August 30, 1991

P-062

Honorable Robert J. Campbell, Chairman
Members, Joint Legislative Audit Committee
State Capitol, Room 2163
Sacramento, California 95814

Dear Mr. Chairman and Members:

The Office of the Auditor General presents its report concerning the drug benefit portion of the Medi-Cal program. The report compares strategies that Medi-Cal uses to manage the cost of the drug benefit portion of Medi-Cal to strategies that various private and public health care providers use in their health care programs.

We conducted this audit to comply with Chapter 1643, Statutes of 1990.

Respectfully submitted,

A handwritten signature in cursive script, reading "Kurt R. Sjöberg".

KURT R. SJÖBERG
Auditor General (acting)

**How Medi-Cal and Other Health Care Providers
Manage Their Pharmaceutical Expenditures**

P-062, August 1991

**Office of the Auditor General
California**

CAAG/DHS0071159
CAAG/DHS0071159

Table of Contents

Summary	S-1
Introduction	1
Chapter 1 Strategies Used by Twelve Major Pharmaceutical Purchasers To Control Pharmaceutical Expenditures	7
Chapter 2 Attempts To Control the Growth In Medi-Cal Drug Expenditures	21
Appendices	
A Canadian Drug Pricing Policies and Utilization Controls	41
B The Effect of Open Versus Restricted Formularies on Medicaid Expenditures	45
C Discussion of Selected Aspects of the Medi-Cal Drug Benefit Program	53
D Pharmaceutical Manufacturers' Costs	57
E Percent of Health Maintenance Organizations (HMOs) Using Various Techniques To Control Pharmaceutical Costs	59
F References Cited	61
Response to the Audit Health and Welfare Agency Department of Health Services	63

Summary

Results in Brief Chapter 1643 of the Statutes of 1990 requires the Office of the Auditor General to conduct a study of the drug contracting program of the California Medical Assistance Program (Medi-Cal). We conducted this study to compare Medi-Cal's strategies with the strategies various private and public health care providers use to manage the cost of the drug benefit portions of their health care programs. Based on our surveys of Medi-Cal prescribing physicians, 12 major pharmaceutical purchasers, interviews of officials of the Medi-Cal program, and our review of numerous studies on the subject of the rising cost of pharmaceuticals, we can make the following observations:

- Medi-Cal drug expenditures grew from \$231 million in 1984 to an estimated \$516 million in 1989, or by 124 percent. This growth in expenditures is due to both an expanded use of the Medi-Cal drug benefit and also an increase in the average cost per prescription.
- Twelve major pharmaceutical purchasers we surveyed employ a wide variety of strategies designed to control their expenditures for pharmaceuticals. These controls fall into two broad categories--utilization and price. Utilization controls monitor or restrict the amounts and types of drugs for which the pharmaceutical purchaser pays whereas price controls contain pharmaceutical costs by limiting the price that purchasers pay for drugs.

S-1

Office of the Auditor General

- In an attempt to stem increases in Medi-Cal expenditures, Medi-Cal also uses most of the same utilization and price strategies as those identified by the major pharmaceutical purchasers we surveyed.
- In July 1990, legislation was passed that established a drug discount program designed to reduce the prices that Medi-Cal pays for drugs.
- For a sample of six prescription drugs, we surveyed six pharmacists on what amounts they would bill Medi-Cal and we determined what amounts they would be reimbursed. We found that for the same prescription drug, a significant difference exists in the amounts pharmacies would have billed Medi-Cal and the amounts Medi-Cal would have reimbursed the six pharmacies.
- The variation in amounts of reimbursements among the six pharmacies revealed that a significant difference exists in what Medi-Cal would have reimbursed the six pharmacies for the same drug.

Background

Medi-Cal is an \$8.7 billion program funded jointly by the state and federal governments and administered by the California Department of Health Services (department). Medi-Cal provides health care services to low-income persons and families, the medically needy, and public assistance recipients. Medi-Cal beneficiaries are entitled to a variety of medically necessary services including physician care, hospital care, psychological counseling, and prescription drugs.

**Strategies
To Control
Expenditures**

The 12 major pharmaceutical purchasers we surveyed, which included government entities, hospitals, hospital buying groups, and health maintenance organizations, use a wide variety of techniques to control pharmaceutical costs. These techniques

Summary

fall into either one of the two categories of utilization and price control.

Utilization controls include drug formularies, which are lists of drugs and dosages that a major pharmaceutical purchaser believes to be the most useful and cost-effective; generic substitution which is the substitution of chemically identical but less expensive generic drugs instead of more expensive brand name drugs; therapeutic substitution which is the substitution of chemically different but therapeutically equivalent drugs; drug education programs to change or influence physicians' prescribing habits; drug utilization reviews to identify physicians who prescribe drugs inappropriately; dispensing controls at the pharmacy level to limit the quantity dispensed and to ensure beneficiary eligibility; and beneficiary copayments to discourage beneficiaries from purchasing unnecessary drugs.

Price controls include limits on the amounts major pharmaceutical purchasers will reimburse a pharmacy for filling prescriptions, and price discounts that purchasers negotiate directly with pharmaceutical manufacturers.

The pharmaceutical purchasers we surveyed use the techniques discussed above in a variety of combinations to control drug costs. Major pharmaceutical purchasers such as government entities and buying groups, which are less active in applying drug utilization controls, focus their efforts on price control, using volume purchasing as a tool to negotiate manufacturer price discounts. These organizations also negotiate price discounts by entering "bundling" agreements, agreeing to purchase multiple-source drugs from a particular vendor in exchange for a price discount on that vendor's single-source drugs. (Drug vendors consist of manufacturers and wholesalers.) Hospitals and health maintenance organizations use both utilization and price controls to contain drug costs.

S-3

Office of the Auditor General

**Attempts
To Control
Medi-Cal
Drug Costs**

Medi-Cal uses many of the same utilization controls to contain pharmaceutical costs as the drug purchasers we surveyed, but until recently, Medi-Cal's price control efforts focused exclusively on pharmacy reimbursement limits. However, in July 1990, the department established a drug discount program to negotiate with drug manufacturers for price discounts. The department estimated that the drug discount program will save the state and federal governments \$3.3 million in fiscal year 1990-91. However, this estimate does not take into account a budgeted \$659,000 cost to the State associated with operating the program.

In addition to obtaining discounted prices for pharmaceuticals, the drug discount program is also designed to simplify the addition of new drugs to Medi-Cal's list of contract drugs (which has now replaced the formulary). Before implementing the program, the department could add new drugs to the formulary only through a regulation process, which, for two drugs that we researched, took approximately 15 months. Under the drug discount program, the department can add new single-source drugs to the list of contract drugs whenever the department and a manufacturer negotiate a rebate contract. For two drugs that we researched, adding these drugs through the negotiation process took approximately four months for one drug and seven months for the other.

**Agency
Comments**

The Department of Health Services believes our report contains a fair and reasonable assessment of how third parties, including Medi-Cal, control pharmaceutical expenses while maintaining access to needed drug products.

Introduction

Chapter 1643 of the Statutes of 1990 requires the Office of the Auditor General to conduct a study of the drug benefit portion of the California Medical Assistance Program (Medi-Cal). We conducted this study to compare Medi-Cal's strategies with the strategies various private and public health care providers used to manage the cost of the drug benefit portions of their health care programs.

Medi-Cal and Prescription Drug Costs

The federal Health Care Financing Administration (HCFA) oversees the Medicaid program, which, together with state governments, provides basic health services, including prescription drugs, to public assistance recipients, low-income individuals and families, and medically needy individuals. Through Medicaid, the federal government provides matching funds to states that have instituted medical care programs, such as Medi-Cal. Medi-Cal is an \$8.7 billion program funded jointly by the state and federal government and administered by the California Department of Health Services (department). Authorized by Title XIX of the federal Social Security Act and Section 14000 et seq. of the state Welfare and Institutions Code, Medi-Cal provides health care services to public assistance recipients, low-income individuals and families, and the medically needy. During fiscal year 1990-91, an average of four million persons qualified for Medi-Cal services each month. Under the program, Medi-Cal beneficiaries are entitled to a variety of medically necessary services, including physician care, hospital care, psychological counseling, and prescription drugs.

Office of the Auditor General

In recent years, prescription drug expenditures for Medi-Cal beneficiaries have continued to increase. According to a 1990 study prepared by SysMetric/McGraw-Hill, Inc., Medi-Cal drug expenditures grew from \$231 million in 1984 to an estimated \$516 million in 1989, or by 124 percent. This means that Medi-Cal's drug expenditures grew by a compounded rate of 17 percent during each year between 1984 and 1989.

This growth in drug expenditures is not unique to California. In a June 1991 study completed for our office, Price Waterhouse reported that national expenditures for drugs and other medical items grew from \$20.1 billion in 1980 to \$41.9 billion in 1988. This represents an increase of 108.5 percent, or a compounded annual rate of growth of 9.6 percent between 1980 and 1988. In a January 1991 study prepared for the Michigan Pharmacists Association, Public Sector Consultants, Inc., reported that Michigan's prescription drug costs for Medicaid recipients grew from \$71.6 million in fiscal year 1982 to \$156.6 million in fiscal year 1989. This represents an increase of 119 percent, or a compounded annual rate of growth of 11.8 percent between fiscal year 1982 and fiscal year 1989.

The SysMetric/McGraw-Hill study attributes the growth in Medi-Cal drug expenditures to both an increase in average cost per prescription and the expanded use of the Medi-Cal drug benefit program. This rise in average cost per prescription accounted for 39 percent of the increase in Medi-Cal expenditures between 1984 and 1989. Growth in the number of Medi-Cal beneficiaries receiving prescription drugs and in the number of prescription drugs used by each Medi-Cal patient accounts for 61 percent of the growth in Medi-Cal drug expenditures.

This report will focus on current efforts by Medi-Cal and other health care providers to stem the increases in the prices they pay for pharmaceuticals. Also, the report will detail various strategies that Medi-Cal and the other health care providers use to ensure that the drug benefit portions of their health care programs are used only when necessary.

Introduction

**Pharmaceutical
Distribution
System**

According to a report prepared for the HCFA, the system of distribution of pharmaceuticals in the United States involves more than 750 U.S. drug manufacturers or pharmaceutical companies, more than 86 drug wholesalers, and about 55,000 pharmacies. The manufacturers that do not distribute their own product rely on the 86 wholesalers that operate the nearly 300 wholesale distribution centers in the United States. For the individual pharmacy, the wholesaler reduces the number of transactions necessary for purchasing a full line of drug products. Without the wholesaler, an individual pharmacy would have to purchase from several hundred manufacturers weekly or monthly. In most metropolitan areas, wholesalers can deliver drugs with same-day service, and nearly all communities have access to next-day service. Medi-Cal beneficiaries rely on community pharmacies throughout the State to fill their prescriptions.

**Scope and
Methodology**

Chapter 1643 of the Statutes of 1990 requires our office to collect information on how various private and public health care providers, including the department, are managing the price of drugs associated with the drug benefit portion of their health care programs. The statutes specifically direct that we determine how various health care providers secure reasonable or lowest prices on the single- and multiple-source drugs they buy. A single-source drug is a drug that is marketed by only one manufacturer or distributor. A multiple-source drug is a drug that is marketed by two or more manufacturers or distributors or by both.

We are also required to determine what types of dispensing fees these health care providers have in place, whether these health care providers have established copayments, and how such requirements affect beneficiaries and providers. Further, we are required to determine how open and restricted formularies and the list of contract drugs affect the cost of a health care program and beneficiaries' access to drugs. An open formulary is a compilation of all drug products that are available for use in a target patient population. A restricted formulary restricts the

Office of the Auditor General

list of drug products. Drugs may be left off a formulary because of one or more of the following: they are considered less than effective; they are available over the counter; they are used for cosmetic purposes and are not considered essential to the patient's health; they are subject to patient misuse and abuse; or the program does not wish to cover them for administrative, cost, or other reasons. Medi-Cal's formulary contained more than 500 drugs and identified drugs that could be provided to Medi-Cal beneficiaries without receiving prior authorization from the department. In July 1990, the Medi-Cal formulary became the list of contract drugs.

In addition, the statutes require that we determine whether federal reimbursement limits influence the inclusion of certain drugs on the Medi-Cal list of contract drugs or influence Medi-Cal beneficiaries' access to those drugs. The list of contract drugs includes all drugs previously listed on the Medi-Cal formulary except for those drugs deleted as a result of contract negotiations between the department and manufacturers or for those drugs the department suspends from the list.

We were also required to determine whether different pharmacies charge the Medi-Cal program different amounts for the same drugs. Further, we were required to determine the percent of the national market that Medi-Cal represents for single-source breakthrough drugs and to collect information on the pharmaceutical manufacturers' costs associated with the research, development, production, and marketing of single- and multiple-source drugs. We defined breakthrough drugs as those drugs classified by the Food and Drug Administration (FDA) as either a new molecular entity offering significant therapeutic gain (known as a "1A" drug) or a high-priority AIDS drug (known as a "1AA" drug).

To identify strategies various major pharmaceutical purchasers use to manage the pharmaceutical cost portions of their health care programs, we surveyed, either by phone or in person, officials of the department's Medi-Cal pharmaceutical program, the California Department of General Services, Los Angeles County, the United States Department of Veterans Affairs, two Canadian

Introduction

government entities, four hospitals or hospital buying groups (hospitals that associate to purchase pharmaceuticals as a group), and five health maintenance organizations. Throughout this report, we refer to these various organizations as "major pharmaceutical purchasers." (We present the information we obtained on the actions of two Canadian government entities to regulate the price of pharmaceuticals in Appendix A.) We also reviewed, when possible, these organizations' formularies; their descriptions of drug plan benefits, policies, and procedures; and their annual reports. In addition, we reviewed research reported in various health care journals and studies provided by professional organizations within the health care industry.

We contracted with a pharmaceutical economist to determine the effect of open and restricted formularies on program costs. (We present his work on this issue in Appendix B.) In addition, to assess the effect of formularies and prior authorization requirements on Medi-Cal beneficiaries' access to drugs, we surveyed more than 400 physicians who served Medi-Cal patients in fiscal year 1989-90 concerning the physicians' willingness to prescribe drugs not included on Medi-Cal's list of contract drugs. (We present these issues in Appendix C.)

To determine the effect of federal reimbursement limits on the department's inclusion of certain drugs on Medi-Cal's list of contract drugs and on Medi-Cal beneficiaries' access to drugs, we interviewed department officials who are involved in adding drugs to the list of contract drugs. (We discuss the effect of federal reimbursement limits on Medi-Cal's list of contract drugs and on beneficiaries' access to drugs in Appendix C.) In addition to reviewing the effect of federal reimbursement limits, we surveyed six pharmacists concerning the prices they charge for a sample of six multiple-source drugs. We compared the amounts that each pharmacy would have charged to Medi-Cal with state and federal reimbursement limits.

We attempted to determine Medi-Cal's percentage of the national market for single-source breakthrough drugs. The expenditure data that we reviewed were limited to expenditures

Office of the Auditor General

for retail pharmacies and do not reflect Medi-Cal or national expenditures for drugs administered in hospital settings. We were able to obtain both Medi-Cal and national expenditure data on only 2 of the 15 breakthrough drugs approved by the FDA from 1988 through 1990. For one of the drugs, Ifex, which is used to treat cancer, Medi-Cal spent less than one hundredth of one percent of national expenditures in 1990. For the other drug, Diflucan, used to treat AIDS, Medi-Cal spent \$624,000 in calendar year 1990, which represents 3.9 percent of national expenditures for the drug.

To determine pharmaceutical manufacturers' costs for research, development, manufacturing, and marketing, we reviewed the 1990 annual reports for four companies whose pharmaceutical sales represented at least 70 percent of their net sales. We also reviewed the annual reports of three additional companies that reported pharmaceutical research and development costs separately from costs for the remainder of their business. (We present this information in Appendix D.)

Finally, in Appendix E, we present statistics concerning the pharmaceutical management practices of a large sample of health maintenance organizations throughout the United States.

Chapter 1 Strategies Used by Twelve Major Pharmaceutical Purchasers To Control Pharmaceutical Expenditures

Chapter Summary

Our review of relevant literature and our survey of major pharmaceutical purchasers other than the California Medical Assistance Program (Medi-Cal) revealed a variety of strategies that major pharmaceutical purchasers may employ to control the increase in their expenditures on pharmaceuticals. The strategies, or controls, fall into two broad categories—utilization and price. Utilization controls monitor or restrict the amounts and types of drugs for which the major pharmaceutical purchaser pays whereas price controls contain pharmaceutical costs by limiting the price that purchasers pay for drugs. This chapter discusses the utilization and price strategies available for controlling pharmaceutical expenditures and how the 12 major pharmaceutical purchasers we surveyed are applying those controls.

Utilization and Price Controls

In its January 1990 report—Skyrocketing Prescription Drug Prices: Turning a Bad Deal Into a Fair Deal—the United States Senate Special Committee on Aging surveyed pharmacy directors at 63 U.S. hospitals, 50 state Medicaid programs, 12 major health maintenance organizations, and 4 large hospital and nursing home prescription drug buying groups. The report concluded that federal and state governments pay higher prescription drug prices through their Medicaid programs than any other major purchasers of prescription drugs. In its August 1989 report—Prescription Drug Prices: Are We Getting Our Money's Worth?—the committee reported that some organizations, such as the Department of Veterans Affairs, hospitals, and health maintenance organizations are negotiating prices directly with pharmaceutical manufacturers at discounts of 41 to 99 percent off the published average wholesale price.

To determine how organizations other than Medi-Cal negotiate favorable pharmaceutical prices and what methods they use to control the utilization and cost of prescription drug benefits, we surveyed various entities. These entities are three government organizations, the United States Department of Veterans Affairs, the County of Los Angeles, and the California Department of General Services; four hospitals or hospital buying groups that purchase pharmaceuticals for hospitals; and five health maintenance organizations that either purchase pharmaceuticals or pay for pharmaceuticals that intermediaries, such as pharmacies, purchase and provide to the organizations' members or beneficiaries. In this chapter we refer to all of the organizations as major pharmaceutical purchasers.

Methods for controlling pharmaceutical costs fall into two main categories: utilization controls and price controls. Utilization controls monitor or restrict the amounts and types of prescription drugs for which the major pharmaceutical purchaser will pay. Utilization controls include drug formularies, generic substitution, therapeutic substitution, prescriber education programs, drug utilization reviews, dispensing controls, and beneficiary copayments. Price controls contain prescription drug costs by limiting the price that major pharmaceutical purchasers pay for pharmaceuticals. These controls include pharmacy reimbursement limits and negotiated price discounts.

Drug Formularies

A drug formulary is a list of drugs and dosages that a major pharmaceutical purchaser believes to be the most useful and cost-effective for patient care. Formularies are usually established by pharmacy and therapeutics committees that may comprise physicians, pharmacists, other health care professionals, and administrators.

In deciding whether to include a drug on the formulary, a pharmacy and therapeutics committee may consider factors such as the drug's effectiveness, side effects, ease of administration, and cost and the availability of other drugs to treat the same

Chapter 1

condition. The committee may also identify certain drugs or classes of drugs that the major pharmaceutical purchaser will not cover under any circumstances. Commonly excluded items include over-the-counter drugs, drugs used for cosmetic purposes, and drugs prescribed for uses other than those approved by the United States Food and Drug Administration.

Formularies may vary in their restrictiveness. One type of formulary is merely a guideline for physicians to use when prescribing drugs, and physicians are free to prescribe non-formulary drugs for beneficiaries without restriction. Other formularies may require physicians to consult with the pharmacy and therapeutics committee or a clinical pharmacist and obtain authorization to prescribe a non-formulary drug.

Generic Substitution

Generic or multiple-source drugs are prescription drugs that are not covered by a patent and are available from multiple vendors. The National Pharmaceutical Council defines generic substitution as "the act of dispensing a different brand or an unbranded drug product for the drug product prescribed (i.e., chemically the exact same drug in the same dosage form, but distributed by different companies)." Major pharmaceutical purchasers may require pharmacists to substitute a brand name product with a less expensive identical product whenever such a product is available when a physician writes a prescription for the brand name product. Physicians may override automatic generic substitution by indicating on the prescription that generic substitution is not permitted or that the brand name drug is medically necessary. Some major pharmaceutical purchasers allow beneficiaries to request a brand name drug instead of a generic but require the beneficiary to pay additional charges to receive the brand name drug.

Office of the Auditor General

Therapeutic Substitution

Therapeutic substitution, usually used to save money, is the replacement of one drug with a chemically different but therapeutically equivalent drug. Pharmacy and therapeutics committees may prepare a list of therapeutically equivalent drugs that pharmacists may substitute without consulting the prescribing physician. Alternatively, pharmacists may contact physicians directly to request approval before making a therapeutic substitution. Substitution is allowed only in cases in which the substituted drug will result in the same therapeutic benefit for the patient. Therapeutic substitution may allow a major pharmaceutical purchaser to ensure use of the least expensive of the equivalent drugs. According to one of the major pharmaceutical purchasers we surveyed, such substitution can also increase the purchase volume of the preferred substitute. This increased purchase volume may allow the major pharmaceutical purchaser to negotiate an even more favorable price with the manufacturer. By using only one drug among several therapeutic equivalents, major pharmaceutical purchasers may encourage price competition among the manufacturers of the equivalent drugs.

"H2 antagonists" are one example of a therapeutic class of prescription drugs that contains several chemically different drugs of varying prices, all of which physicians prescribe to treat ulcers. A physician might prescribe one particular H2 antagonist for a patient, and the pharmacist could dispense another, less expensive one after either consulting an approved list of therapeutic equivalents for the prescribed drug or consulting directly with the prescribing physician. Other therapeutic classes that contain several chemically different but therapeutically equivalent drugs are blood pressure medications, antibiotics, and non-steroidal anti-inflammatory drugs.

Prescriber Education Programs

Major pharmaceutical purchasers may attempt to change or influence the prescribing habits of physicians by offering prescriber education programs. These programs take many forms. Some use

Chapter 1

periodic newsletters containing information on prescription drug costs and the availability of new generic drugs while others use a combination of printed information and personal contacts between physicians and clinical pharmacists. For example, one of the purchasers we surveyed stated that therapeutic classes containing numerous drugs of varying cost for treating the same condition have been the focus of recent educational campaigns. The campaigns attempt to raise physicians' awareness of when they can and should prescribe the least costly drug therapy and when they may need to prescribe one of the more costly alternatives. In at least one prescriber education program, the major pharmaceutical purchaser severely restricts contact between physicians and representatives of prescription drug manufacturers so that the physicians will not be subject to the representatives' sales presentations for non-formulary drugs or drugs that are not cost-effective.

Research has shown that educating physicians about drug utilization can be a cost-effective method of reducing Medicaid drug expenditures. In their 1986 article "Economic and Policy Analysis of University-based Drug 'Detailing,'" Soumerai and Avorn reported the results of a controlled test involving 435 office-based physicians in three states and the District of Columbia. The authors found that physician education resulted in a 13 percent cost savings to Medicaid in the nine months following the test in comparison with a control group that did not receive such education. In the test, physician education consisted of printed information accompanied by face-to-face interactions between clinical pharmacists and physicians. Such education was designed to reduce the number of prescriptions for three drugs for which safer or more cost-effective therapies were available. Soumerai and Avorn then estimated the costs and benefits of providing the same educational program to 10,000 physicians over six months. Based on the results of their controlled test, they estimated that the expanded program would result in a net benefit to Medicaid of \$111,000 per 1,000 physicians over six months, assuming no substitution of over-the-counter drugs for the three drugs, and \$66,000 per 1,000 physicians, assuming a large substitution of over-the-counter drugs for the three drugs.

Chapter 1

In addition to dispensing limits, some major pharmaceutical purchasers told us they require pharmacies to consult an electronic data base to verify a beneficiary's eligibility to receive drugs and the amount of copayment the beneficiary must pay. One of these major pharmaceutical purchasers that also requires prior authorization for non-formulary drugs told us the data base allows the pharmacist to determine, before dispensing, whether the drug is on the formulary. If the drug is not on the formulary, the pharmacist can call either the physician, for authorization to dispense a different drug, or the major pharmaceutical purchaser, to receive authorization to dispense the non-formulary drug. If a major pharmaceutical purchaser allows therapeutic substitution, the data base may also allow the pharmacist to identify appropriate therapeutic substitutes. Computerized beneficiary files may also allow the pharmacist to assess the appropriateness of a given drug therapy for a beneficiary in relation to other prescription drugs the beneficiary may already be using.

Copayments

Major pharmaceutical purchasers sometimes require their members or beneficiaries to share the cost of each prescription they receive by making a small cash payment or a copayment to the pharmacy at the time of purchase. For the purchasers we surveyed, these copayments ranged from no copayment to \$12 per prescription. At least one of the major pharmaceutical purchasers we surveyed requires a higher copayment if a member or beneficiary receives a brand name drug when a less expensive generic drug is available.

In their 1990 article "Experience of State Drug Benefit Programs," Soumerai and Ross-Degnan point out that copayments are designed to reduce beneficiaries' use of unnecessary drugs, and evidence exists that they do reduce drug use. In their 1984 article "The Effect of a Medicaid Drug Copayment Program on the Utilization and Cost of Prescription Services," Nelson Jr., et al., reported that copayments appeared to have decreased the number of prescriptions per beneficiary when South Carolina

implemented a 50 cents-per-prescription copayment for Medicaid beneficiaries. However, Soumerai and Ross-Degnan also note that it is unlikely that many patients have enough information about their prescriptions to decide which are necessary and which are not, and thus, a copayment could result in patients not receiving needed care.

Pharmacy Reimbursement Limits

Some major pharmaceutical purchasers will cover a beneficiary's prescription only if the patient fills the prescription at a pharmacy with which the major pharmaceutical purchaser has a contract (contract pharmacy). These contracts limit pharmacy reimbursements by specifying a formula by which the major pharmaceutical purchaser will reimburse the pharmacy for filling members' or beneficiaries' prescriptions.

One common reimbursement limit is the average wholesale price (AWP) of the drug less a percentage discount plus a dispensing fee. The AWP is a composite price set by manufacturers and reported in commercial publications. In a 1989 report, the Office of the Inspector General of the federal Department of Health and Human Services determined that the AWP is, on average, at least 15 percent greater than the actual price pharmacies pay to acquire drugs. Some major pharmaceutical purchasers require contract pharmacies to provide a fixed percentage discount off the AWP and, then, add a dispensing fee to compensate the pharmacy for overhead. For example, if a major pharmaceutical purchaser had a contract to reimburse a pharmacy for 100 tablets of a drug at an AWP of \$10 minus 10 percent plus a dispensing fee of \$3.50, the major pharmaceutical purchaser would compute the reimbursement price for the drug as follows:

Chapter 1

Commercially published AWP for 100 tablets of the drug	\$10.00
Minus 10 percent discount	(1.00)
Subtotal	9.00
Plus dispensing fee	3.50
Total reimbursement for 100 tablets of the drug	\$12.50

According to one of the major pharmaceutical purchasers we surveyed, pharmacies are willing to enter into these contract reimbursement formulas because the major pharmaceutical purchaser can provide the pharmacy with an increased volume of business.

In addition to reimbursement formulas based on the AWP, at least two of the major pharmaceutical purchasers we surveyed set a maximum allowable cost (MAC) for generic drugs since these drugs are available from several sources at varying prices. The MAC is the highest price the major pharmaceutical purchaser will reimburse the pharmacy for a generic drug. The two major pharmaceutical purchasers establish the MAC for a given drug by reviewing prices charged by various manufacturers of generic drugs.

Negotiated Price Discounts

Some major pharmaceutical purchasers told us they negotiate contracts for price discounts directly with prescription drug manufacturers. In these instances, the purchasers' primary tool for negotiating discounts with prescription drug manufacturers is the purchasers' ability to influence the volume of sales of a manufacturer's product. Also, purchasers may use their formularies and their prescriber education programs to encourage the use of a particular prescription drug or a particular manufacturer's brand of a multiple-source prescription drug and, thus, generate increased sales volume for that drug.